

## § 522.960b

## 21 CFR Ch. I (4–1–14 Edition)

### § 522.960b Flumethasone acetate solution.

(a) *Specifications.* Each milliliter of solution contains 2 milligrams (mg) of flumethasone acetate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer by intramuscular injection as follows: Dogs weighing up to 10 pounds (lbs): 2 mg; dogs weighing 10 to 25 lbs: 4 mg; dogs weighing over 25 lbs: 8 mg. Dosage should be adjusted according to the weight of the animal, the severity of the symptoms, and the response noted. Dosage by injection should not exceed 3 days of therapy. With chronic conditions intramuscular therapy may be followed by oral administration of flumethasone tablets at a daily dose of from 0.0625 to 0.25 mg per animal.

(2) *Indications for use.* For use in certain acute and chronic canine dermatoses of varying etiology to help control the pruritus, irritation, and inflammation associated with these conditions.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

### § 522.960c Flumethasone solution.

(a) *Specifications.* Each milliliter of solution contains 0.5 milligrams (mg) of flumethasone.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* Administer 1.25 to 2.5 milligrams (mg) daily by intravenous, intramuscular, or intra-articular injection.

(ii) *Indications for use.* For use in the treatment of musculoskeletal conditions due to inflammation, where permanent structural changes do not exist, e.g., bursitis, carpalis, osselets, and myositis; and allergic states, e.g., hives, urticaria, and insect bites.

(iii) *Limitations.* Do not use in horses intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Dogs*—(i) *Amount.* Administer 0.0625 to 0.25 mg daily by intravenous,

intramuscular, or subcutaneous injection; 0.125 to 1.0 mg daily by intralesional injection, depending on the size and location of the lesion; or 0.166 to 1.0 mg daily by intra-articular injection, depending on the severity of the condition and the size of the involved joint.

(ii) *Indications for use.* For use in the treatment of musculoskeletal conditions due to inflammation of muscles or joints and accessory structures where permanent structural changes do not exist, e.g., arthritis, osteoarthritis, disc syndrome, and myositis (in septic arthritis, appropriate antibacterial therapy should be concurrently administered); certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation; otitis externa in conjunction with topical medication; allergic states, e.g., hives, urticaria, and insect bites; and shock and shock-like states by intravenous administration.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(3) *Cats*—(i) *Amount.* Administer 0.03125 to 0.125 mg daily by intravenous, intramuscular, or subcutaneous injection.

(ii) *Indications for use.* For use in the treatment of certain acute and chronic dermatoses of varying etiology to help control associated pruritus, irritation, and inflammation.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[79 FR 16188, Mar. 25, 2014]

### § 522.970 Flunixin.

(a) *Specifications.* Each milliliter of solution contains flunixin meglumine equivalent to 50 milligrams (mg) flunixin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) See Nos. 000061, 055529, and 061623 for use as in paragraph (e) of this section.

(2) See No. 054771 for use as in paragraph (e)(1) of this section.

(3) See Nos. 057561 and 059130 for use as in paragraphs (e)(1) and (2) of this section.